Investigator's (Study) Document Files

1. **FDA Form 1572:** Signed FDA Form 1572 and any additional 1572 forms that reflect additions or changes/additions of study investigator or co/sub-investigators

2. **Protocol:** Signed copy of final protocol and any modifications or amendments

3. **CVs:** Curriculums Vitae for the Principal Investigator and any co/sub-investigators and the study medical monitor

4. **Personnel and Training:** A list of all study personnel (except investigators) with their qualifications and documentation of training

5. **Signatures:** A signature list of principal investigator, co/sub-investigators, monitors and study personnel corresponding with their printed names and initials, as used in study document notations

6. **Laboratory Certification:** including CV of any clinical laboratory director(s) of any laboratory used for the study and any Clinical Laboratory Institute for Accreditation (CLIA), College of American Pathologists (CAP) or other certification/accreditation

7. **Clinical Laboratory Normal Values**: ranges of normal laboratory values which will be referenced during the trial

8. **Committee Approvals:** Scientific Review Committee, Local IRB, if any, and HSRRB

9. **Deviations:** Current documentation of any deviations that have occurred during the trial

10. **Investigator's Brochure**

11. **Drug Accountability**: receipt, disposition, return, destruction

12. **Standard Operating Procedures:** any SOPs specific to the study; at minimum, 1) Drug Accountability, 2) Obtaining Valid Informed Consent, 3) Adverse Event Reporting, 4) Data Management and Security, 5) Protocol Deviations/Modifications, 6) Clinical Laboratory Procedures including Quality Controls, 7) Specimen Handling, 8) Equipment Maintenance and Calibration

13. **Monitor/Quality Assurance Visit Log:** include date, name, organization and purpose of visit; DO NOT include reports or other records of comments resulting from these visits

14. **Subject Screening, Enrollment and Disposition Log**

15. **Equipment:** inventory, maintenance, calibration

16. **Correspondence:** any memoranda of telephone conversations, other memoranda, notes, E-mail, letters or other study-pertinent written records

17. **Progress Reports**

18. **Adverse Events:** records of any adverse events that occurred during the study and reports of resolution of all adverse events

19. **Final Report**

20. **Case Report Forms**